American Hospital Association®

Regulatory Advisory

November 7, 2014

CMS Proposes Updates to Requirements for Home Health Agencies

At a Glance

At Issue:

On Oct. 9, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a proposed rule to revise the current Conditions of Participation (CoPs) for home health agencies (HHAs) that participate in Medicare and Medicaid. The proposed rule would modify many of the current CoPs, reorganize their structure and add several new quality-related requirements, including standards for:

- care planning and coordination;
- quality assessment and performance improvement (QAPI); and
- infection prevention and control.

CMS also proposes to expand regulations related to patients' rights, among other changes, and emphasizes a patient-centered approach throughout the rule. The CoPs generally apply to all patients served by HHAs, not just Medicare beneficiaries.

Our Take:

We applaud CMS for continuing to update the CoPs for health care providers to ensure that regulations are current, reflect the best and most recent knowledge about care delivery, and embody high expectations for quality of care. We expect that the proposals may require some HHAs to make changes in their operations. AHA seeks input on the feasibility of implementing these changes, as well as appropriate timeframes for implementation. For example, HHAs would need to formalize quality assessment and infection control programs (pages 8-10 of this advisory). CMS also would expand regulations related to the discharge and transfer of patients (pages 4,5 and 8), and change the required qualifications for HHA administrators (page 18).

What You Can Do:

- ✓ Share this advisory with the leaders involved in any HHA services you provide, including any administrators, physician/nursing leaders, quality and compliance managers and risk managers.
- ✓ **Please ask relevant HHA staff members to participate in a members-only call on Friday, Nov. 14 at 12 p.m. ET to provide input on the proposed changes.** To register for the call, please visit **www.surveymonkey.com/s/HKNXK67**.
- ✓ Alternatively, share your feedback about this proposed rule with AHA at homehealthfeedback@aha.org**.**
- ✓ Submit comments directly to CMS on the proposed rule**,** describing how the proposed changes would impact your organization's ability to provide high-quality care to patients. **Public comments are due to CMS no later than 5 p.m. ET on Dec. 8.**

Further Questions:

Contact Evelyn Knolle, AHA senior associate director of policy, at (202) 626-2963 or eknolle@aha.org.

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BACKGROUND

The Medicare program covers home health services, as defined in § 1861(m) of the Social Security Act (SSA), to beneficiaries who are under the care of a physician.[1] Currently, home health agencies (HHAs) that provide services to Medicare and Medicaid beneficiaries must meet Conditions of Participation (CoPs) that govern how services are provided and define federal safety and operational standards. As the Centers for Medicare & Medicaid Services (CMS) interprets the SSA, the home health CoPs apply to all individuals served by a HHA, except where a requirement is limited to Medicare beneficiaries.

On Oct. 9, CMS published in the *Federal Register* a proposed rule to revise the current HHA CoPs. In the rule, CMS conveys its intent to:

- Promote care coordination;
- Emphasize a patient-centered, interdisciplinary approach to care;
- Encourage quality improvement;
- Eliminate requirements that may not be very helpful in achieving clinically relevant outcomes or preventing harm; and
- Safeguard patient rights.

The proposed rule would eliminate some of the current CoPs, and reorganize, retain and/or enhance other requirements. It also would add several new categories of quality-related requirements related to care planning and coordination, quality assessment and performance improvement (QAPI) and infection prevention and control. Further, CMS proposes to expand regulations related to patients' rights, among other changes. Through the proposed CoPs, CMS hopes to foster continuing and ongoing quality assessment and performance improvement. CMS emphasizes "a shared commitment between CMS and HHA providers to achieve improvements in the quality of care furnished to HHA patients."

In the rule, CMS also discusses the pervasiveness of disparities in health care, and asks for specific comments about how the proposed requirements can be used to address disparities.

AT ISSUE

Under the proposed rule, the HHA CoPs would be organized into three sections: Subpart A – General Provisions; Subpart B – Patient Care; and Subpart C, Organizational Environment.

[1] These services can include part-time or intermittent skilled nursing care (furnished by or under the supervision of a registered professional nurse); physical therapy, speech-language pathology, and occupational therapy; medical social services under the direction of a physician, part-time or intermittent home health aide services; medical supplies and durable medical equipment; services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program, and services at hospitals, skilled nursing facilities, or rehabilitation centers when they involve the use of equipment that makes it difficult to provide the items and services at a beneficiary's residence, such as equipment that is too cumbersome to bring home.

Proposed Subpart A – General Provisions

CMS proposes to reorganize and amend Subpart A, which covers the basis and scope of the regulations and definitions. CMS states that the regulations will provide a foundation for survey activities to determine whether HHAs meet the requirements to participate in Medicare. Subpart A also includes definitions. CMS proposes to:

- modify the definition of HHA "branch office." Among other changes, CMS proposes to require a parent agency to provide supervision and administrative control.
- make minor changes to definitions for "clinical note," "parent home health agency," "proprietary agency," "subdivision" and "summary report."
- eliminate definitions for "bylaws," "supervision," "HHA," "nonprofit agency," "progress notes," and "subunit." Subunits and parent HHAs currently may share the same governing body, administration and professional personnel. But according to CMS, subunits already have their own provider numbers and must independently meet the CoPs. In the proposed rule, these subunits would be considered by CMS to be independent HHAs and would be required to meet independently all CoPs without sharing a governing body or administrator. However, subunits could, depending on state requirements, become branches of their current parent HHAs.
- add definitions for "in advance," "quality indicator," "representative," "supervised practical training," and "verbal order."
- clarify the definition of "primary home health agency."
- retain the current definition of "public agency."

For a description of all proposed definitions, please see Appendix A.

Proposed Subpart B – Patient Care

The newly reorganized Subpart B would cover standards for information privacy, patient rights, assessments, care coordination, performance improvement, infection control, skilled services and home health aide services.

Release of patient identifiable outcome and assessment information set (OASIS) data. Currently, HHAs are required to report data electronically to CMS based on comprehensive patient assessments. CMS proposes to retain, but recodify, current requirements for a HHA and its agents to ensure the confidentiality of all patient-identifiable information in the clinical record, including OASIS data.

Reporting OASIS information. CMS proposes to make minor modifications in how HHAs electronically report OASIS data. Among other changes, CMS would replace an outdated requirement to transmit data using electronic communications software that provides a direct telephone connection to the state agency or relevant contractor. Instead, CMS proposes to require that OASIS data be transmitted in accordance with current CMS transmission policy, which requires the use of software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 25, 2001).

Patient rights. CMS proposes to reorganize and expand upon the current requirements pertaining to patient rights.

Notice of rights. Similar to current regulation, the proposed rule states that the patient and his or her representative (if any) have the right to be informed of the patient's rights. CMS would clarify that this information must be in a language and manner the individual understands. CMS would keep the requirement that the HHA must protect and promote the exercise of these rights.

Under the proposed rule, the HHA would need to provide the patient and representative (if any) the following information during the initial evaluation visit, prior to furnishing care:

- written notice of the patient's rights and responsibilities, which will be understandable to people with limited English proficiency and accessible to people with disabilities (free of charge); and
- verbal notice of the patient's rights and responsibilities in the individual's primary or preferred language and in a manner the individual understands, free of charge, using a competent interpreter if needed. (The patient or representative may use his or her own interpreter, but the HHA must ensure the communication is effective.)

If a patient cannot communicate effectively, the HHA may provide information to the representative in his or her preferred language. The HHA must obtain the patient's/representative's signature confirming receipt of a copy of notice of rights and responsibilities. In addition, the HHA must provide contact information for the administrator (to receive complaints or questions) and the OASIS privacy notice to patients for whom OASIS data are collected.

Exercise of rights. CMS recognizes that there are many situations in which patient representatives may be used and proposes new language to address these various situations. Under the proposed rule, the patient's rights may be exercised by:

- someone appointed by a state court to act on the patient's behalf, if the patient has been adjudged incompetent under state law by a court of proper jurisdiction;
- the patient's representative (in accordance with the patient's wishes), if a state court has not adjudged the patient incompetent; and
- the patient himself/herself, to the extent allowed by court order, if the patient has been adjudged to lack legal capacity under state law by a court of proper jurisdiction.

CMS specifically seeks public comment on ways to assure that patient choice is respected while also balancing the need to assure patient safety.

Rights of the patient. CMS slightly expands the current list of patient rights, augments some standards, and reorganizes these requirements under a new section titled, "Rights of the Patient." Under the proposed rule, the patient would have the right to:

- have his or her person and property treated with respect;
- be free from verbal, mental, sexual and physical abuse, including injuries of unknown source, neglect and misappropriation of property;
- make complaints to the HHA regarding care, unfurnished treatment or lack of respect for person or property;

- participate in, be informed about, and consent/refuse care before or during treatment, where appropriate, with respect to a number of factors such as the assessment; the plan of care and any changes; frequency of visits; the disciplines that furnish the care; expected outcomes, including goals, risks and benefits; and factors affecting treatment effectiveness;
- receive all services outlined in the plan of care;
- have clinical records kept confidential and in compliance with federal privacy laws;
- be free from discrimination or reprisal for exercising his or her rights or voicing grievances; and
- be informed of the right to access auxiliary aids and language services and how to access them.

HHA patients also would retain the right to be advised about the extent to which services will be covered by Medicare, Medicaid or another federal program known to the HHA, and how much they may have to pay, before care is initiated. The HHA must advise patients of changes in coverage when they occur as soon as possible, before the next HHA visit. The revised requirements also would reference additional patient notice regulations. The proposed rule states clearly that patients have the right to be provided with proper written notice, before care is furnished, that the care may not be covered, or before the HHA reduces or terminates care.

Further, patients also must be provided relevant information about the state toll free home health telephone hotline that receives complaints or questions about local HHAs, as well as relevant information about pertinent publicly funded state and local consumer information, consumer protection and advocacy agencies.

Transfer and discharge. Under the proposed rule, HHAs must inform the patient and representative (if any) of its policies for admission, transfer and discharge before care is provided. CMS proposes that the HHA may transfer or discharge a patient only when:

- the HHA and physician responsible for the home health plan of care agree that the HHA can no longer meet the patient's needs, based on the patient's acuity. In this case, the HHA must ensure a safe and appropriate transfer to other care entities;
- the patient or payer will no longer pay for services;
- the HHA and the physician responsible for the home health care plan agree that services are no longer necessary because the patient's health and safety have improved or stabilized sufficiently;
- the patient refuses services or elects to be transferred or discharged;
- the HHA determines the patient should be discharged for cause. Discharge for cause is based on disruptive, abusive or uncooperative behavior (by the patient or another person in the patient's home) that seriously impairs the HHA's ability to care for the patient or operate effectively. The HHA must document in the clinical record the problems and how the HHA attempted to resolve them. Further, the HHA must have a policy for addressing discharge for cause that includes the following requirements before discharging for cause:

    - The HHA must advise the following individuals that a "for cause" discharge is being considered: the patient, representative (if any), the physician who is responsible for the home health plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA;
    - The HHA must make efforts to resolve the problem(s) presented by the patient's behavior, the behavior of other persons in the patient's home, or the situation;
    - The HHA must provide the patient and representative (if any) with contact information for other agencies or providers who may be able to provide care.
- The patient dies; or
- The HHA stops operating.

Investigation of complaints. CMS proposes to expand current regulations pertaining to investigations of complaints. Under the proposed rule, HHAs would be required to investigate complaints made by the patient, the patient's representative (if any), or the patient's caregivers and family about:

- Treatment or care that is:
    - furnished
    - not furnished
    - furnished inconsistently
    - furnished inappropriately

- Mistreatment, neglect, verbal, mental, sexual, and physical abuse, including injuries of an unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA. Further, staff members employed either directly or under arrangement by the HHA must immediately report any noticeable incidences of any of these types of abuses to the HHA and appropriate authorities.

The HHA must document complaints and their resolutions and must take action to prevent further violations while investigating a complaint.

Accessibility. Under the proposed rule, CMS would require that information be provided to patients in plain language, in a manner that is accessible and timely, and at no cost to persons with:

- disabilities, including accessible web sites and auxiliary aids and services, in Accordance with the Americans with Disabilities Act and § 504 of the Rehabilitation Act; and
- limited English proficiency, through language services.

Comprehensive Assessment of Patients. Under the proposed rule, for the most part CMS retains and reorganizes current regulations. However, CMS would expand requirements slightly for HHAs to provide a comprehensive, patient-specific assessment to each patient. For example, CMS proposes to add a new standard, "Content of the comprehensive assessment." This section would require that the comprehensive assessment include at a minimum:

1. The patient's current health, psychosocial, functional and cognitive status;
2. The patient's strengths, goals and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;
3. The patient's continuing need for home care;
4. The patient's medical, nursing, rehabilitative, social and discharge planning needs;
5. A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy and noncompliance with drug therapy;
6. The patient's primary caregiver(s), if any, and other available supports;
7. The patient's representative (if any); and
8. Incorporation of the current version of the OASIS items, using the language and groupings of the OASIS items, as specified by the Health and Human Services (HHS) Secretary. The OASIS data items determined by the HHS Secretary must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

CMS would retain current regulations related to how often the comprehensive assessment must be updated, with a few revisions. For example, currently the comprehensive assessment must be updated within 48 hours of the patient's return home from a hospital admission of 24 hours or more for any reason other than diagnostic tests. CMS would add the words, "*or on physician-ordered resumption date"* to this requirement. Thus the new requirement would state that the assessment must be updated, "[w]ithin 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests, or on physician-ordered resumption date."

Care Planning, Coordination of Services, and Quality of Care

Plan of care. Among other requirements, the proposed rule states that each patient must have an individualized written plan that specifies the care and services necessary to meet the patient's needs as identified in the comprehensive assessment. The plan should identify the responsible disciplines and measurable goals and outcomes expected and specify patient and caregiver education and training to be provided by the HHA. CMS clarifies that the plan must be established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry acting within the scope of his or her state license, certification, or registration.

CMS also discusses the value of a shared decision-making model, "where there is a mutually respectful exchange that recognizes the individuality of the patient and a process in which responsibility is divided among the patient, physician, and agency acting on physician orders…" **CMS specifically seeks comment regarding methods to engage patients and the physicians who are responsible for their plans of care in the care planning and management process.**

CMS also would expand the list of items that need to be included in each individual plan of care. Each care plan would need to contain:

1. All pertinent diagnoses;
2. The patient's mental, psychosocial and cognitive status;
3. The types of services, supplies and equipment required;
4. The frequency and duration of visits to be made;
5. Prognosis;
6. Rehabilitation potential;
7. Functional limitations;
8. Activities permitted;
9. Nutritional requirements;
10. All medications and treatments;
11. Safety measures to protect against injury;
12. Patient and caregiver education and training to facilitate timely discharge;
13. Patient-specific interventions and education, as well as measurable outcomes and goals identified by the HHA and the patient;
14. Information related to any advanced directives; and
15. Any additional items the HHA or physician may choose to include.

Further, if HHA services follow a hospital admission, the plan of care must describe the risk for emergency department visits and readmissions, as well as "all necessary interventions to address the underlying risk factors." Finally, CMS emphasizes in the proposed rule that all patient care orders (including verbal orders) would need to be recorded in the care plan.

Conformance with physician orders. The proposed regulation reiterates that drugs, services and treatments must be administered only as ordered by the physician responsible for the plan of care, with the exception that influenza and pneumococcal vaccines may be administered per a HHA policy developed with a physician, after assessment of the patient for contraindications. Similar to current regulations, the proposed rule would require verbal orders to be accepted only by personnel authorized to do so by applicable state laws and regulations and by the HHA's internal policies.

CMS clarifies in the proposed rule that when verbal orders are used, a registered nurse (RN) or other qualified practitioner responsible for furnishing or supervising the ordered services must document verbal orders in the patient's clinical record, and sign, date and record the time of the orders. In addition, verbal orders must be authenticated and dated by the physician per state requirements and HHA policies.

Review and revision of the plan of care. Similar to current regulations, the proposed rule would require that the HHA and the physician responsible for the home health plan of care review and revise the care plan as often as needed, "but no less frequently than once every 60 days, beginning with the start of care date." The HHA must alert the physician about any changes in the patient's condition that suggest poor outcomes or the need to alter the plan of care. CMS would require that the revised plan of care reflect information from the updated comprehensive assessment as well as progress toward outcomes and goals. When a care plan is revised due to changes in patient health status, revisions would

need to be communicated to the patient, representative (if any), caregiver, and physician responsible for the care plan. When discharge plans are revised, the changes would need to be communicated to the patient, representative, caregiver, physician, and the primary care practitioner or other health care practitioner who will provide care/services after discharge (if any).

Coordination of care. CMS proposes to expand the standard for coordination of care. The proposed rule would require HHAs to integrate services to ensure that patient needs and factors affecting safety and treatment effectiveness are identified; that the care provided by all disciplines is coordinated; and that there is communication with the physician. The HHA would be required to coordinate care and to involve the patient, representative (if any) and caregivers (if appropriate). The HHA also must provide ongoing training and education to patients and caregivers about care and services identified in the plan of care that the patient/caregiver will implement, including post-HHA discharge activities.

Discharge or transfer summary. CMS proposes new standards for what must be included in the discharge or transfer summary. These items include:

1. A summary of the patient's stay, including:
    - the reason for referral to the HHA;
    - the patient's clinical, mental, psychosocial, cognitive, and functional condition at the time of the start of services by the HHA;
    - all services provided by the HHA;
    - the start and end date of care by the HHA;
    - the patient's clinical, mental, psychosocial, cognitive, and functional condition at the time of discharge from the HHA;
    - an updated reconciled list of medications at the time of discharge or transfer; and
    - any recommendations for ongoing care (for example, outpatient physical therapy).
2. The patient's current plan of care, including the latest physician orders.
3. Any other documentation that will assist in post-discharge or transfer continuity of care, or that is requested by the health care practitioner who will be responsible for providing care and services to the patient after discharge from the HHA or receiving facility.

Quality Assessment and Performance Improvement (QAPI). CMS proposes to add new requirements for HHAs to have QAPI programs. Specifically, HHAs would need to implement, maintain, document and evaluate ongoing, HHA-wide, data driven QAPI programs that reflect the complexity of the HHA services (including those provided under contract); use indicators related to improved outcomes; and proactively address performance. CMS would remove two current CoPs at § 484.16 and § 484.52 related to the review of a HHA's policies and performance.

The regulations would require HHAs to measure, analyze and track quality indicators to assess HHAs' performance. These efforts include using OASIS measures, where applicable, and other relevant data to monitor effectiveness, safety and quality of services and identify opportunities for improvement. The HHA must be able to demonstrate

measurable improvement in indicators with potential to improve health outcomes, safety and quality. The regulations would require HHAs to conduct and document distinct performance improvement projects annually, in accordance with the complexity, scope, and past performance of their services.

In conducting performance improvement activities, CMS expects HHAs to focus on high-risk, high-volume, or problem-prone areas; consider incidence, prevalence and severity of problems in those areas; and initiate immediate correction of identified problems that could threaten the health and safety of patients. In addition, CMS expects HHAs to track adverse events; analyze their causes; and implement preventive actions. HHAs also must make sure that any improvements are sustained.

The HHA's governing body must approve the data collection process and ensure that an ongoing QAPI program is defined, implemented and maintained. In addition, it must ensure that QAPI efforts address priorities for improved quality of care and patient safety and are evaluated. The governing body also must establish, implement and maintain clear expectations for patient safety and address findings of fraud or waste.

CMS believes that small and midsize HHAs could implement these requirements without inordinate expenditure of capital or human resources. CMS suggests helpful resources on page 61176 of the rule.

AHA asks members to provide feedback about this QAPI proposal, including how much effort would be needed to select measures, track quality indicators, and implement performance improvement activities. Does your HHA already do this, and if not, how much time would be needed to come into compliance with this proposed requirement?

Infection Prevention and Control. CMS proposes that HHAs develop, maintain and document agency-wide infection prevention and control programs, based on a three-pronged approach that includes prevention, control and education. Through these new requirements, CMS seeks to protect patients and health care workers (and others in the environment) and to do so in a manner that is timely, effective and cost-efficient when possible.

Under the proposed rule, HHAs would be required to:

- follow accepted standards of practice, such as standard precautions; and
- as an integral part of its QAPI program, maintain a coordinated, agency-wide program for surveillance, identification, prevention, control and investigation of infectious and communicable diseases and problems. This requirement includes having a plan for "the appropriate actions that are expected to result in improvement and disease prevention."

CMS recognizes that the HHA staff cannot completely control the environment in a patient's home. But the agency believes that implementing best practices, such as using gloves when handling blood products, can reduce risks of infections and communicable diseases. CMS expects that HHAs will work with their health departments to develop their

programs. In addition, the HHA must provide infection control education to staff, patients and caregivers. The exact content and frequency of the education would be left to the discretion of HHAs but should include current best practices.

AHA asks members to provide feedback about the infection control program proposal, including how much effort would be needed to develop and implement a program. Does your HHA already conduct surveillance to identify, prevent, and control infectious and communicable diseases? If not, how much time would be needed to come into compliance with this proposed requirement?

Skilled Professional Services. CMS would add a new section in the regulation that consolidates several existing CoPs for skilled nursing services, therapy services, and medical social services and delineates requirements for skilled professional services. This CoP would describe skilled professional services as including skilled nursing services, physical therapy, speech-language pathology services, occupational therapy, and physician and medical social work services. CMS expects skilled professionals (even those providing services under arrangement) to participate in coordination of care.

Only professionals who meet certain personnel qualifications, as outlined in proposed § 484.115 (describing personnel qualifications), could authorize, deliver and supervise skilled professional services. They must practice according to the HHA policies and procedures.

CMS expects skilled professionals to assume responsibility for:

1. Ongoing interdisciplinary assessment of the patient;
2. Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s);
3. Providing services ordered by the physician as indicated in the plan of care;
4. Patient, caregiver and family counseling;
5. Patient and caregiver education;
6. Preparing clinical notes;
7. Communication with the physician who is responsible for the home health plan of care and other health care practitioners (as appropriate) related to the current plan of care;
8. Participation in the HHA's QAPI program; and
9. Participation in HHA-sponsored in-service training.

CMS also includes supervision requirements in the proposed rule, specifically:

- A RN that meets the requirements of proposed § 484.115(j) must supervise nursing services.
- An occupational therapist or physical therapist that meets the requirements of proposed § 484.115(e) or (g), respectively must supervise rehabilitative therapy services.
- A social worker that meets the requirements of proposed § 484.115(l) must supervise medical social services.

Home Health Aide Services. CMS proposes to modify, reorganize and consolidate current requirements related home health aide services. In the proposed rule, CMS says it would require home health aides to have successfully completed one of the following:

1. A training and competency evaluation program as specified in proposed §§ 484.80(b) and 484.80(c);[2] or
2. A competency evaluation program that meets the requirements of proposed § 484.80(c); or
3. A nurse aide training and competency evaluation program approved by the state as meeting the requirements of proposed §§ 483.151 through 483.154 of this chapter,[3] and is currently listed in good standing on the state nurse aide registry; or
4. The requirements of a state licensure program that meet the requirements of proposed §§ 484.80(b) and 484.80(c).

However, if there is a 24-month (or longer) lapse in which the aide did not furnish services for compensation, he or she must complete another program. CMS notes that HHAs may add additional training requirements to address special needs of the HHA's patient population.

Current requirements governing the content of home health aide training programs include 13 subject areas, which are retained without major revisions in the proposed regulations. However, CMS proposes two new categories for training. First, CMS would add a new requirement to ensure that training programs address how to recognize and report changes in skin condition, such as pressure ulcers. Second, CMS proposes a requirement to train home health aides for skills needed but not covered in the basic checklist for personal hygiene and grooming tasks.

CMS expands a current requirement related to communication skills. CMS would require that aides be able to read, write and verbally report clinical information to patients, representatives, caregivers and HHA staff. CMS recognizes that many languages may exist in a community, and the agency says HHAs should try to "match patients with staff relative to their abilities to communicate with one another."

The duration of training and documentation requirements would be the same. CMS would continue to require a total of at least 75 hours of classroom and supervised practical training. CMS reiterates that "[a] minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours."

Competency evaluation. In the proposed rule, CMS maintains a current standard stating that an individual may furnish home health services only after successfully completing a competency evaluation program. The competency evaluation would need to address each of the same components as the proposed 15 training requirements. CMS would require

[2] Proposed § 484.80(b) addresses the content and duration of home health aide training and identifies 15 categories of skills needed for such training. Proposed § 484.80(c) describes the subjects to be covered in competency evaluations, how the evaluations should be conducted, who may perform them, and how results should be interpreted.

[3] Sections 483.151 through 483.154 cover state home health aide training and competency evaluation programs.

certain skills to be demonstrated by observation (versus written or oral evaluation), such as communication skills; reading and recording vital signs; personal hygiene and grooming techniques; safe transfer techniques; and normal range of motion and positioning criteria. CMS believes it is acceptable to perform training with a mannequin and to conduct competency evaluations with a "pseudo-patient," which CMS describes as an individual (such as a volunteer or another aide) whose age reflects the primary population served by the HHA. As in current regulation, a RN would need to perform the competency evaluation. However, CMS proposes that the evaluation be conducted in consultation with other skilled professionals, as appropriate, to ensure that competency is demonstrated in each area.

CMS also proposes to modify who must supervise an aide performing a task for which he or she was rated "unsatisfactory." A RN, not a licensed practical nurse, would need to supervise such a task until the aide achieves a subsequent evaluation of "satisfactory."

Eligibility to train and evaluate. CMS proposes to keep and slightly expand the current regulation that home health aide training and evaluation can be provided by any organization unless it falls under one of seven specified exceptions. The exceptions include, for example, agencies that had compliance deficiencies in the previous two years. CMS proposes to add as a new exception HHAs that were excluded from participating in federal health care programs or banned from participating in any government program.

Training instructor qualifications. CMS also would require that classroom and supervised practical training must be performed by a RN who has a minimum of two years nursing experience, at least one year of which must be in home health care, or by other individuals under the general supervision of the RN.

In-service training. In the proposed rule, CMS separates the regulations for competency evaluations and in-service training. The proposed rule retains the minimum number of in-service annual training hours at 12. CMS expects that the start dates for this annual period would be an aide's date of hire or calendar year, as defined by the HHA. CMS would continue to allow in-service training to be offered by any organization, and the training could take place while an aide provided patient care. A RN must supervise the training, but the RN would no longer need a minimum of two years nursing experience with at least one year in home health care. The HHA must document in-service training.

Home health aide assignments and duties. CMS retains most of the regulations describing home health aide assignments and duties and enhances them slightly. Under the proposed rule, home health aides would have to be assigned to a specific patient by a RN or other appropriate skilled professional (that is, a physical therapist, speech-language pathologist, or occupational therapist). Aides must receive written patient care instructions prepared by a RN or other appropriate skilled professional responsible for the supervision of a home health aide as specified by regulations. As in current regulations, home health aides will be expected to provide services that are ordered by the physician, included in the plan of care, and permitted to be performed under state law. CMS proposes to add a provision that services should be consistent with the home health aide training.

The proposed rule includes current regulations pertaining to the duties of a home health aide, which include the provision of hands-on personal care; the performance of simple

procedures as an extension of therapy or nursing services; assistance in ambulation or exercises; and assistance in administering medications ordinarily self-administered.

A new provision would require home health aides to be members of the interdisciplinary team; to report changes in the patient's condition to a RN or other appropriate skilled professional; and to complete appropriate records in compliance with the HHA's policies and procedures. CMS states, "Home health aides may observe changes in patient needs that are crucial to future treatment decisions, and these changes should be reported to the appropriate HHA professional in order to implement effective and appropriate changes in care."

Supervision of home health aides. CMS proposes to differentiate supervision requirements based on the skill level of the care required by the patient. CMS proposes that when a patient receives skilled nursing, physical or occupational therapy or speech-language pathology care, the home health aide supervisor (a RN, physical therapist, speech-language pathologist, or occupational therapist) must visit the patient's home at least every 14 days. The home health aide would not need to be present. However, CMS also would require "as needed observation" visits by the supervisor if potential deficiencies in care are noted. During these visits, the supervisor would observe the aide while he or she provided care to the patient. HHAs also would be required to make an annual site visit to at least one patient's home to assess each home health aide as he or she delivers care, though HHAs could conduct more "interaction observations" as necessary to achieve a full assessment of the aide's capabilities.

For patients who do not receive skilled care, the RN must make a site visit to the location where the patient is receiving care at least every 60 days to assess each home health aide while he or she delivers care.

If an onsite visit reveals deficiencies in care provided, the HHA must conduct, and the aide must complete, a competency evaluation.

CMS also would clarify that supervision must ensure that aides deliver care safely and effectively, including:

- following the patient's plan of care for completion of tasks assigned to a home health aide;
- maintaining an open communication process with the patient, representative (if any), caregivers and family;
- demonstrating competency with assigned tasks;
- complying with infection prevention and control policies and procedures;
- reporting changes in the patient's condition; and
- honoring patient rights.

CMS also proposes to keep regulations for services provided under arrangement[4] by aides who are not HHA employees. If a HHA provides services under arrangement, it is at least

[4] Services under arrangement are defined at §1861(w)(1), which states that, "The term 'arrangements' is limited to arrangements under which receipt of payment by the hospital, critical access hospital, skilled

expected to ensure the overall quality of care provided by an aide; supervise aide services as described above; and ensure that home health aides have met the training or competency evaluation requirements of this proposed regulation.

Medicaid personal care services. CMS reiterates that a Medicare-certified HHA may provide services to Medicaid patients under a state Medicaid personal care benefit. But CMS clarifies that these individuals must meet all qualification standards established by the states before providing care and must demonstrate competency in the services they are required to furnish.

Proposed Part C – Organizational Environment

Compliance with laws and regulations. CMS proposes to retain most of the current regulations for compliance with federal, state and local requirements *related to the health and safety of patients.*

Disclosure of ownership. CMS would continue to require compliance with Medicare program integrity regulations about disclosure of ownership and control. HHAs would still be required to disclose information about ownership and control, officers and directors, corporate management, and more to a state survey agency when initially requesting certification, for each survey, and when changes in ownership or management occur.

Licensing. In states with licensure requirements, CMS would require HHAs, their branches, and employees who provide services to patients be licensed, certified, or registered, as applicable.

Lab services. If the HHA engages in laboratory testing, it must comply with applicable Medicare requirements pertaining to laboratories at 42 CFR 493. This requirement does not pertain to helping a patient self-administer a test with an appliance that has been cleared by the Food and Drug Administration. CMS reiterates that a HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests. However, HHAs may use their own equipment to complement a patient's equipment to ensure accuracy or for short periods of time while a patient is waiting to receive his or her own equipment. CMS would expect the HHA to use available resources to help a patient obtain his or her own testing equipment as soon as possible.

In addition, if a HHA refers specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services according to federal Medicare laboratory requirements at 42 CFR 493, which incorporate the standards of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Organization and Administration of Services. CMS proposes to simplify and expand the current regulations related to organizational structure and administration. CMS would expect HHAs to manage their resources to achieve and maintain "the highest practicable functional capacity" for each patient. Under the proposed rule, the HHA cannot delegate

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nursing facility, home health agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services."

administrative and supervisory functions to another organization. The HHA must have its organizational structure, lines of authority and services in writing.

Governing body. The agency proposes to expand the responsibilities of the governing body to include full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and its operational plans, and its quality assessment and performance improvement program.

Administrators. CMS changes some of the requirements for administrators. Under the proposed rule, administrators must be: appointed by the governing body, responsible for the day to day operations of the HHA, and responsible for ensuring that a skilled professional is available at all operating hours. Note that the current State Operations Manual (SOM) describes availability as being on the premises of the HHA or reachable via telecommunications. The SOM defines "operating hours" as all hours that agency staff provide services to patients.

CMS proposes that when the administrator is not available, the HHA has a pre-designated person who is authorized in writing by the administrator and governing body to assume the administrator's responsibilities and obligations. CMS expects the administrator and the pre-designated person to meet the requirements for administrators under "Personnel Qualifications" below.

Clinical manager. CMS proposes a new clinical manager role. CMS believes that having a designated clinical manager will address unmet needs for care coordination and written and updated care plans. Under this proposed requirement, a qualified licensed physician or RN must oversee all patient care services and personnel. This oversight includes:

1. Making patient and personnel assignments;
2. Coordinating patient care by the various patient care disciplines;
3. Coordinating referrals;
4. Assuring that patient needs are continually assessed;
5. Assuring the development, implementation and updates of the individualized plan of care; and
6. Assuring the development of personnel qualifications and policies.

Parent-branch relationships. CMS also proposes a new standard for relationships between a parent HHA and its branch locations. Under this requirement, the parent HHA would be responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and when the parent HHA proposes to add or delete a branch. In addition, the parent HHA must provide direct support and administrative control of its branches.

CMS expects that:

- the lines of authority and professional and administrative control are clear;
- the HHA parent knows about the staffing, patient census and any issues affecting branch operations;

- the administrator of the HHA continually ensures that staff are competent and able to provide appropriate, adequate, effective and efficient patient care so as to ensure that any clinical and/or other emergencies are immediately addressed and resolved;
- the HHA parent monitors branch activities; and
- the HHA parent is responsible for contracted arrangements used by the branch.

CMS provides guidance for the approval of a branch office in the SOM and notes that its system of assigning identification numbers to branches, which is included on OASIS assessments, can help a HHA monitor quality at the branch level.

Services under arrangement. HHAs may provide services under arrangement with another agency, organization or individuals. CMS would make changes to provisions governing services provided under arrangement. Under the proposed rule, services furnished under arrangement must meet the requirements of these HHA regulations and section 1861(w) of the SSA. As in current regulations, a HHA must have a written agreement with another entity or individual to furnish services under arrangement to the HHA's patients. However, the proposed rule states that the HHA must maintain overall responsibility for the services provided under arrangement.

The entity or individual providing services under arrangement may not have:

1. Been denied Medicare or Medicaid enrollment;
2. Been excluded or terminated from any federal health care program or Medicaid;
3. Had its Medicare or Medicaid billing privileges revoked; or
4. Been banned from participating in any government program.

Services furnished. HHAs must offer skilled nursing services and one of the therapeutic services (physical therapy, speech-language pathology, occupational therapy; medical social services; or home health aide services) on a visiting basis in the patient's home. A HHA must provide at least one of the services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization. CMS would delete a reference to "part-time or intermittent" services from current provisions, but these terms continue to exist under coverage and eligibility requirements. In addition, CMS would require that all HHA services be provided in accordance with current clinical practice guidelines in addition to accepted professional standards of practice.

Clinical Record Requirements. CMS would change some of the clinical record requirements. Under the proposed rule, the HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician who is responsible for the home health plan of care and appropriate HHA staff. This information may be maintained electronically. CMS says in the preamble of the rule that the record must demonstrate consistency among the diagnosis, plan of care and actual care furnished.

Contents of clinical record. The proposed rule expands the required content of clinical records, which would need to include:

1. The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician orders;
2. All interventions, including medication administration, treatments, and services, and responses to those interventions;
3. Goals in the patient's plans of care and the patient's progress toward achieving them;
4. Contact information for the patient and the patient's representative (if any);
5. Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA; and
6. A completed discharge or transfer summary, as required by proposed § 484.60(e), that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within seven calendar days of the patient's discharge. Alternatively, if the patient's care will be immediately continued in a health care facility, a discharge or transfer summary is sent to the facility within two calendar days of the patient's discharge or transfer.

Authentication. CMS proposes to add a new requirement related to authentication of clinical records. In the proposed rule, CMS says all entries must be legible, clear and complete, and they must be appropriately authenticated, dated and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry.

Record retention. CMS would revise standards for the retention of records. The proposed regulation requires clinical records to be retained for five years *after the discharge of the patient* (versus five years after the relevant cost report is filed with the intermediary), unless state law stipulates a longer period of time. As in current regulation, the HHA's policies must provide for retention of clinical records, even if the HHA discontinues operation. A HHA that discontinues operations must inform the state agency as to where clinical records will be maintained.

Protection of records. CMS also proposes to amend the requirements governing the protection of records. As in current regulation, the clinical record must be safeguarded against loss or unauthorized use. CMS would add a new standard that the HHA must be in compliance with the rules regarding personal health information set out in 45 CFR parts 160 and 164, which pertain to general administrative requirements and the Health Insurance Portability and Accountability Act.

Retrieval of records. CMS also would implement a new standard for the retrieval of clinical records. The agency proposes that a patient's clinical record (whether hard copy or electronic form) must be made available to a patient and appropriately authorized individuals or entities upon request.

Personnel Qualifications. As in current regulation, CMS would require that HHA staff meet specific qualification standards. CMS retains the current qualifications except as noted below. CMS also proposes to delete the qualification category for public health nurses, because they are RNs, and RN qualifications are already included.

Administrator. CMS changes the qualifications for an administrator of a HHA. In current regulations, an administrator must be a licensed physician, RN **or** someone who has training and experience in health service administration with at least one year of supervisory or administrative experience in home health care or related health programs. In the proposed rule, an administrator must be a licensed physician, a RN, *or someone who holds an undergraduate degree*. In addition, the administrator must have experience in health service administration, with at least one year of supervisory or administrative experience in home health care or a related health care program. CMS expects that a HHA's governing board would specify which undergraduate degree could be used. The governing body must appoint the administrator.

CMS does not propose to add financial management training as a requirement for HHA administrators at this time, because CMS believes HHAs often employ or consult a chief financial officer and billing staff. **CMS specifically asks for comment regarding this aspect of the proposed rule.**

Licensed practical nurse. CMS replaces the term "practical (vocational) nurse" with "licensed practical nurse." In the proposed rule, a licensed practical nurse is a person who has completed a practical nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified RN.

Occupational Therapist. In the proposed rule, the qualifications for occupational therapists are almost identical to the current regulation. However, the current regulations allow therapists educated abroad to meet part of the necessary criteria by successfully completing a program that is substantially equivalent to occupational therapist entry level education in the U.S. offered by one of four categories of organizations. In the proposed rule, the therapist must have successfully completed a program that is substantially equivalent to occupational therapist *assistant* entry level education in the U.S. by one of the four categories of organizations.

Occupational Therapy Assistant. The qualifications outlined in the proposed rule for an occupational therapy assistant are almost exactly the same as in current regulation. However, the proposed rule states that an occupational therapy assistant is a person who "[a]fter January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section." There is no paragraph (b)(6)(i) in the proposed rule text. We are seeking clarification of what CMS intended to say.

Physical Therapist. In current regulations, and in the proposed rule, physical therapists must be licensed (if applicable) and must meet one of several additional categories of qualifications. In current regulations, the first category requires physical therapists to have successfully completed a physical therapist education program **and** passed an examination for physical therapists approved by the state. In the proposed rule, the word

"and" is dropped, and the text is renumbered in a way that could imply that either education or passage of an exam is acceptable.

Under current standards, the fifth category requires a physical therapist to have been admitted to membership by the American Physical Therapy Association (APTA); **or** admitted to registration by the American Registry of Physical Therapists; **or** graduated from a physical therapy curriculum in a four-year college or university approved by a state department of education. In the proposed rule, the fifth option includes the above mentioned membership, registration, **and** graduation from a physical therapy curriculum in a four-year college or university approved by a state department of education.

Physical Therapy Assistant. CMS revises the qualifications for physical therapy assistants. Under current regulation, a physical therapy assistant is a person who is licensed (if applicable), registered or certified (if applicable), and meets one of four additional categories of criteria:

- In the first category, an assistant must meet specified educational criteria **and** pass a national exam for physical therapy assistants.
- In the second category, which outlines criteria applicable before 2010, the assistant must be licensed or otherwise regulated by the state. If a state does not license or regulate physical therapy assistants, the assistant must have graduated before 2010 from a two-year college-level program approved by APTA and meet category one criteria.
- The third category, which describes qualifications necessary before 2008, states that where licensure or other regulation does not apply, the individual must have graduated from a two-year college-level program approved by APTA.
- The fourth category, which describes criteria before 1978, indicates that an assistant must be licensed or qualified as a physical therapist assistant and have passed a proficiency exam conducted, approved or sponsored by the U.S. Public Health Service.

Under the proposed rule, a physical therapy assistant is a person licensed, registered or certified as a physical therapy assistant, if applicable, by the state in which the assistant is practicing, unless licensure does not apply. In addition, the assistant must meet one of two other categories of criteria. In the first category, the assistant must meet the same specified education as listed in current regulations. In the second category, the assistant must have passed a national exam for physical therapist assistants before 2010, **and** he/she must meet one of the following criteria:

- Is licensed, or otherwise regulated in the state in which practicing.
- In states where licensure or other regulations do not apply, graduated before 2010 from a two-year college-level program approved by APTA and after Jan. 1, 2010, meets the requirements of paragraph (b)(8) of this section[5].
- Before Jan. 1, 2008, where licensure or other regulation does not apply, graduated from a two-year college level program approved by APTA.
- On or before Dec. 31, 1977, was licensed or qualified as a physical

[5] It is unclear what is meant by the reference to (b)(8) of this section, as there is no (b)(8) in the proposed regulation text.

therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Physician. CMS revises the definition of physician. In the proposed rule, a physician is a person who meets the qualifications specified in 1861(r) of the SSA and implemented in regulations at § 410.20(b).

RN. Under current regulation, a RN must be a graduate of an approved school of professional nursing, who is licensed as a RN by the state in which he or she practices. In the proposed rule, CMS simplifies the qualifications, so that a RN is "[a] graduate of an approved school of professional nursing who is licensed in the state where practicing."

Social work assistant. CMS keeps the qualifications for social work assistants the same, except for clarifying that a social work assistant provides services under the supervision of a qualified social worker.

Social worker. CMS clarifies that a social worker is someone who may have either a master's degree *or a doctoral degree* from a school of social work accredited by the Council on Social Work Education, and has one year of social work experience in a health care setting.

Speech-language pathologist. CMS changes the qualifications described for speech-language pathologists to align more closely with requirements of 1861(ll) of the SSA. CMS proposes that a qualified speech-language pathologist has a master's or doctoral degree in speech-language pathology and is licensed as a speech-language pathologist by the state in which he or she is practicing. CMS believes every state licenses speech-language pathologists. However, if a state does not have licensure, CMS would require speech-language pathologists to have:

- successfully completed 350 clock hours of supervised clinical practicum (or be in the process of accumulating supervised clinical experience);
- performed at least 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and
- successfully completed a national examination in speech-language pathology approved by the HHS Secretary.

Estimates of Burden

In the proposed rule, CMS provides estimates for the time and costs involved for HHAs to comply with the new provisions. For example:

- CMS estimates that some of the proposed requirements would not cause any burden, as they are already standard practice or mandated by other laws. For example, CMS does not believe the requirement to provide information to patients in a manner that can be understood would generally impose a burden, because HHAs must already comply with such standards under Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act, and Section 504 of the Rehabilitation Act.

- CMS says requiring that verbal notification of patient rights be provided in a language and manner the patient understands would likely create a burden. CMS estimates that it would take about five minutes and cost about $5 per patient to describe the content of the notice of rights and obtain a signature from the patient.

- CMS estimates the burden of developing and implementing a QAPI program for non-accredited HHAs only (because the agency believes accredited HHAs would already comply with the proposal). CMS believes that writing the internal policies associated with a QAPI program would take an average of four hours annually per each HHA and cost $63 per hour. CMS envisions that a QAPI committee, consisting of the QAPI coordinator, the HHA administrator and a clinical manger, might meet three times a year for one hour each to identify quality domains and measures (with an estimated cost of $738 per HHA). Further, CMS estimates that it would take one hour per staff member to provide training in data collection (at a cost of $76 per hour per staff member); four hours per month to gather data (at a cost of $1,248); and three hours a year to identify new domains and quality measures (at a cost of $246 per HHA).

- With regard to the proposed requirement that all patient and family complaints be investigated, CMS believes HHAs would need to investigate complaints for about 15 percent of their patients each year. CMS estimates that each investigation would take about two hours, and the total cost of investigating all complaints would be $9,324 per HHA annually. However, CMS notes that accredited HHAs are already required to investigate complaints.

- With regard to the proposed requirements for infection prevention and control programs, CMS believes it would take a non-accredited HHA 1.5 hours per week, or 78 hours per year, to develop and maintain such a program. This would cost $4,919 annually, according to CMS.

We encourage AHA members to review the estimates described on pages 61193-61200 of the rule and provide feedback to AHA about whether these estimates would be accurate for your HHA. For a snapshot of the field-wide estimated impacts, please see Appendix B of this advisory.

NEXT STEPS

The AHA urges hospitals offering HHA services to submit their thoughts to the AHA regarding the provisions noted in the advisory. AHA will submit comments to CMS and encourages members to submit their own comments to CMS on how the proposed rule would affect their home health services and patients. Comments are due by 5 p.m. on Dec. 8 and may be submitted electronically at http://www.regulations.gov. **Please refer to file code CMS-3819-P.**

For questions, please contact Evelyn Knolle, AHA senior associate director of policy, at (202) 626-2963 or eknolle@aha.org.

Appendix A

§ 484.2 Definitions
As used in subparts A, B and C

Branch office means an approved location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written, timed, and dated, and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response, and any changes in physical or emotional condition during a given period of time.

In advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.

Parent home health agency means the agency that provides direct support and administrative control of a branch.

Primary home health agency means the HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable).

Proprietary agency means a private, for-profit agency.

Public agency means an agency operated by a state or local government.

Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.

Representative means the patient's legal guardian or other person who participates in making decisions related to the patient's care or well-being, including but not limited to, a person chosen by the patient, a family member, or an advocate for the patient. The patient determines the role of the representative, to the extent possible.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has branch offices is considered a parent agency.

Summary report means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician.

Supervised practical training means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.

Verbal order means a physician order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.

Appendix B

Summary of the Collection of Information Requirements and Regulatory Impact Analysis by Health Policy Alternatives

CMS discusses the burden and costs associated with collection of information requirements included in the proposed rule. The table below, a modified version of Table 2 in the proposed rule, summarizes these estimates. Underlying assumptions include 11,930 participating HHAs, 5,000 of which are accredited; and 17.8 million Medicare HHA patients, 7.4 million of which are patients in accredited HHAs.

Regulation Section	Respondents	Responses	Hours per response	Hourly cost of reporting	Total cost of reporting
*§484.50(a) New HHAs develop notice of rights	65	65	8	$98	$50,960
*§484.50(a) Update existing patient rights form	11,930	11,930	1	$98	$1,169,140
§484.50(e) Investigation of complaints	6,930	512,820	0.083	$63	$2,692,305
§484.60(a) Plan of care	11,930	14,268,280	0.083	$26	$36,914,598
*§484.65(e) QAPI policies	6,930	6,930	4	$63	$1,746,360
§484.80(a) aide qualifications	11,930	23,860	0.083	$26	$51,688
§484.80(b)aide recordkeeping	11,930	23,860	0.083	$26	$51,688
§484.80(c) aide competency	11,930	23,860	0.083	$26	$51,688
§484.80(d)document in-service training	11,930	286,320	0.083	$26	$620,360
§484.100(a)* ownership disclosure	11,930	11,930	0.083	$98	$97,412
484.100(a) ownership disclosure new HHAs	549	549	1	$98	$53,802
§484.105(h) institutional planning	6,930	6,930	0.5	$98	$339,570
§484.105(h) institutional planning new HHAs	65	65	1.5	$98	$9,604
§484.110(a) discharge summary to next provider	11,930	17,751,840	0.083	$26	$38,462,320
TOTAL	**19,474**	**32,929,239**			**$82,311,495**
* Denotes a one-time information collection requirement					

In addition to the collection of information requirements, the proposed rule also discusses new burdens and other impacts that would result from implementation of the proposed rule. These include verbal notification of patient rights, completion of investigations of patient complaints, institution of a QAPI program in non-accredited HHAs, and development of an organized infection prevention and control program. In addition, some existing requirements would be replaced. These impacts are summarized in the table below, reproduced from the proposed rule. The proposed rule is considered to be a major rule because the overall economic impact is estimated to be $148 million in the first year and $142 million annually in subsequent years.

Summary of estimated burden for all proposed COPs			
CoP	**Total Time**	**Total Cost in Year 1**	**Annual Cost in Year 2 and Thereafter**
Burden and Cost Estimates Associated with Information Collection Requirements	2,786,178 hours	$82,311,495	$79,291,233
Patient rights	2,349,960 hours	$144,074,520	$144,074,520
QAPI	561,330 hours	$26,403,300	$22,993,740
Infection prevention and control	540,540 hours	$34,054,020	$34,054,020
Removal of 60 day summary requirement	-887,592 hours	-$16,864,248	-$16,864,248
Removal of Group of professional personnel requirement	-192,868 hours	-$19,422,040	-$19,422,04012
Removal of Evaluation of the agency's program	-1,359,953 hours	-$102,305,699	-$102,305,699
TOTAL	**3,797,595 hours**	**$148,251,348**	**$141,821,526**

Source: Centers for Medicare and Medicaid Services